UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,873	01/03/2002	Dany Berube	P032	8352

28802 7590 01/07/2004

AFX INC.
47929 FREMONT BLVD
FREMONT, CA 94538

EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3739	9

DATE MAILED: 01/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/039,873	BERUBE ET AL.	
	Examiner	Art Unit	
	Aaron Roane	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 40, 46 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Lundquist et al. (USPN 6,102,886).

Regarding claims 1, 40, 46 and 48, Lundquist et al. disclose an ablative device comprising a flexible tubular elongate member (4), a distal end ablative device (20) with

at least one ablative element (20), a means for deflecting, shaping and/or steering (12), flexible members (28, 34, 36 and 48), one flexible member (48) is located between the means for steering and the distal end of the elongate body and overlaps the ablative element (20) and a handle portion (2) connected to the proximal end of the flexible tubular elongate member (4), see col. 7-9 and figures 3-10. Furthermore, it should be noted that the flexible tubular elongate member (4) defines a longitudinal axis about which an azimuthal angle is inherently defined. It should also be noted that nature of the energy pattern depends upon the cylindrical symmetry shape of the ablative element and since Lundquist et al. disclose an ablative element (RF electrode 20) that is cylindrically symmetric, the ablative energy has uniform cylindrically symmetric pattern.

Regarding claims 2-4, Lundquist et al. further disclose a means for deflecting, shaping and/or steering (12) that is a flexible means for directionally controlling ablative energy emitted from the at least one ablative element. The emission of the ablative energy is inherently radial (with respect to a cylindrically symmetric system), see col. 7-9 and figures 3-10.

Regarding claims 11, 15, 22, 44 and 45, Lundquist et al. further disclose an ablative element in the form of a flexible RF electrode (20), see col. 7-9 and figures 3-10.

Regarding claims 16, 17 and 41, Lundquist et al. further disclose a means for deflecting, shaping and/or steering (12), flexible members (28, 34, 36 and 48), one flexible member

is in the form of a pull wire (48) and is located between the means for means for deflecting, shaping and/or steering and the distal end (to where it is fixed to a distal portion 50) of the elongate body and a handle portion (2) connected to the proximal end of the flexible tubular elongate member (4), see col. 7-9 and figures 3-10. Activation of the steering means results in change of the flexible tubular elongate member (4) going from a linear to deflected configuration.

Regarding claims 19-21, Lundquist et al. further disclose a means for deflecting, shaping and/or steering (12) wherein the predetermined shape is circular (this satisfies the curvilinear recited feature). Also the recited range for the radius of curvature, "about 0.5 cm to about 5.0 cm", is so large that the invention of Lundquist et al. inherently satisfies the claimed feature, see figures 3, 5 and 13.

Regarding claims 29, Lundquist et al. disclose the method of ablating tissue comprising the provision of an elongate tubular (4), a distal end ablative device (20) with at least one ablative element (20), a means for deflecting, shaping and/or steering (12), flexible members (28, 34, 36 and 48), one flexible member (48) is located between the means for steering and the distal end of the elongate body and overlaps the ablative element (20) and a handle portion (2) connected to the proximal end of the flexible tubular elongate member (4), see col. 7-9 and figures 3-10. Furthermore, I) the advancing of the ablation system into a patient's body until it is near the target tissue, II) the advancing of the distal portion of the ablation catheter until it is proximate the target tissue and the application of

ablative energy are inherent. Lundquist et al. also disclose the deflecting of the distal portion, see abstract.

Regarding claim 30, Lundquist et al. further disclose that a lesion forms due to the ablation of the target tissue, see starting on col. 9, line 56 and ending on col. 10, line 20.

Regarding claim 31, Lundquist et al. disclose the claimed invention, see col. 7-9 and figures 3-10. Furthermore, it is inherent that invention disclosed by Lundquist et al. moves the distal portion from a first position to a second position when the means for deflecting, shaping and/or steering is activated.

Regarding claim 35, Lundquist et al. disclose the claimed invention, see col. 7-9 and figures 3-10. Furthermore, due to the cylindrical symmetry of the ablation element disclosed by Lundquist et al., it is inherent that ablation occurs without respect to the azimuth angle.

Regarding claim 36, Lundquist et al. disclose the claimed invention, see col. 7-9 and figures 3-10. The range of 0° to 180° is so broad, it essentially covers all possible angles, that Lundquist et al. inherently satisfy the recited limitations.

Regarding claim 42, Lundquist et al. further disclose at least a portion (50) of the pull wire operably located external and adjacent to the distal portion, see col. 7-9 and figures 3-10, particularly figure 3.

Regarding claim 47, Lundquist et al. disclose a device that inherently emits ablative energy substantially perpendicular to the longitudinal axis of the tubular member. Substantially perpendicular to the longitudinal axis of the tubular member is in direction as the radial direction of a cylindrically symmetric system.

Regarding claims 49, 50 and 52, Lundquist et al. disclose a device capable of performing the recited intended use. The further limiting recitations of claims 49, 50 and 51 are intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 51, Lundquist et al. disclose an at least one ablative element adapted to emit energy in a unidirectional manner. The energy emitted by the RF electrode (20) propagates in the radial direction (of a cylindrically symmetric system) which is unidirectional.

Claims 1, 16, 18 and 23-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Swanson et al. (USPN 6,514,246 B1).

Regarding claims 1 and 16, Swanson et al. disclose systems and methods for forming large lesions using curvilinear electrode elements comprising a handle portion (16), an elongate flexible tubular member (12) having proximal and distal ends, at least one ablative element (10) disposed at the distal end of the elongate flexible tubular member and a means for deflecting (18, 20 and 24) the distal portion of the elongate flexible tubular member, wherein pull wires (24) are used to steer or deflect the distal portion of the elongate flexible tubular member, col. 5 and figures 1 and 6.

Regarding claim 18, Swanson et al. disclose a device capable of performing the recited action of translating the pull wire (24) in order to result in a deflecting transition from preformed shape to linear shape, see col. 7, lines 24-43 and figures 6, 29 and 30.

Regarding claim 23, Swanson et al. further disclose a guiding member (50) having at least one lumen into which the elongate flexible tubular member is slidably disposed, see col. 8, lines 20-54 and figures 10-12B and 16A-18B.

Regarding claims 24-26 and 28, Swanson et al. further disclose elongate flexible tubular members with various preformed configurations, see col. 15, lines 8-33 and figures 16A-18B. Also the recited predetermined radius of curvature, "about 1.0 cm to about 5.0 cm",

is so large that the invention of Swanson et al. inherently satisfies this feature. Additionally, the deflection means inherently contain springy members since the various preformed configurations can assume their preformed shapes whenever they are extended beyond the distal end of the catheter (12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-10, 12-14 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundquist et al. (USPN 6,102,886) in view of Berube et al. (USPN 6,471,696 B1).

Regarding claims 5-10,12-14 and 43, Lundquist et al. disclose the claimed invention including a shielding sleeve located about the RF electrode, see starting on col. 3, line 60 and ending on col. 4, line 33. However, Lundquist et al. fail to explicitly recite motivation for the shielding, any reflecting properties, and/or the recited geometrical structure of the shield. Lundquist et al. also fail an antenna (helical, monopole or lossy transmission line) that serves as the ablation element. Berube et al. provide a two-fold

teaching; I) the use of a shield and II) the use of an antenna. Berube et al. disclose a microwave ablation instrument and teach the inclusion of a reflecting shield (66) in order to redirect "a portion of the electromagnetic field," see abstract and col. 3 and 4. The reflecting shield is substantially planar along the longitudinal axis of the tubular member (14) and is curved in the plane perpendicular to the longitudinal axis of the tubular member (14). Additionally, the reflecting shield disclosed by Berube et al. is convex with respect to the longitudinal axis of the tubular member (14) as viewed from outside the tubular member (14) and concave with respect to the longitudinal axis of the tubular member (14) as viewed from inside the tubular member (14), see figures 2-4, 5A and 5B. Since this reflecting shield is located at the distal portion of the Berube et al. invention which has a directional controlling, deflecting and/or steering means (see col. 3, lines 46-55 and figures 1-5B and 9), it is inherent that the reflecting shield is part of the distal portion and therefore comprises part of the directional controlling, deflecting and/or steering means of invention in the Lundquist et al. reference. Additionally, Berube et al. teach the use of a linear antenna (64) in order to radiate ablative energy, see abstract. Berube et al. also disclose that it a wide variety of antenna geometries will work as well, where Berube et al. specifically cite helical geometry, see starting on col. 4, line 53 and ending on col. 5, line 17. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Lundquist et al., as taught by Berube et al. to include a reflecting shield in order to redirect "a portion of the electromagnetic field" and to use of a linear antenna, including a wide variety of antenna geometries such as a helical geometry in order to radiate ablative energy.

Claim 27 rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al. (USPN 6,514,246 B1) in view of Sharkey et al. (USPN 6,517,568 B1).

Regarding claim 27, Swanson et al. disclose the claimed invention except using a springy member made from "superelastic material". Sharkey et al. disclose catheter device (14) and tech the use of a springy member (the "pre-bent" or biased" means) made from "superelastic material" such that the springy member may have a linear configuration within the guide member and obtain a curved configuration when extended outside the guide member, see starting on col. 11, line 58 and ending on col. 12, line 13. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Swanson et al., as taught by Sharkey et al., to use a springy member (the "pre-bent" or biased" means) made from "superelastic material" such that the springy member may have a linear configuration within the guide member and obtain a curved configuration when extended outside the guide member.

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundquist et al. (USPN 6,102,886).

Regarding claims 33 and 34, Lundquist et al. disclose the method of ablating tissue comprising the provision of an elongate tubular (4), a distal end ablative device (20) with at least one ablative element (20), a means for deflecting, shaping and/or steering (12),

flexible members (28, 34, 36 and 48), one flexible member (48) is located between the means for steering and the distal end of the elongate body and overlaps the ablative element (20) and a handle portion (2) connected to the proximal end of the flexible tubular elongate member (4), see col. 7-9 and figures 3-10. Furthermore, I) the advancing of the ablation system into a patient's body until it is near the target tissue, II) the advancing of the distal portion of the ablation catheter until it is proximate the target tissue and the application of ablative energy are inherent. Lundquist et al. also disclose the deflecting of the distal portion, see abstract. Finally, it is well known in the art to hollow body organs may be among the ablated tissue.

Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundquist et al. (USPN 6,102,886) in view of Pomeranz et al. (USPN 5,800,482).

Regarding claims 37-39, Lundquist et al. disclose the claimed invention except for explicitly translating the ablative device along the desired tissue, which subsequently creates a long continuous lesion and lesion path. Pomeranz et al. disclose an apparatus and method for linear lesion ablation and teach that it is well known in the art to "drag" the ablative device or tip across the treatment tissue while ablative RF energy is applied in order to "burn linear lesions into the" treatment tissue, see col. 1, lines 30-38. Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Lundquist et al., as taught by Pomeranz et al., to

"drag" the ablative device or tip across the treatment tissue while ablative RF energy is applied in order to "burn linear lesions into the" treatment tissue.

Response to Amendment

The examiner acknowledges the amendments made to the specification and the drawings and that they overcome the previously made objections.

Applicant's arguments filed 10/21/03 have been fully considered but they are not persuasive.

The amendments made to claims 1, 40, 46 and 48 does not overcome the prior art relied upon. The target tissue may be ablated by both the catheter devices disclosed by Lundquist et al. and Swanson et al. since each elongate catheter shaft has a rigid straight proximal portion and a flexible and steerable/deflectable distal portion and is therefore independent of the approach angle. The approach angle is defined by the rigid straight proximal portion of the elongate catheter shaft and target tissue site and since both catheter devices have steerable/deflectable distal end portions, ablation can commence in the predetermined/desired energy pattern independent of the approach angle.

The amendments to claims 29 and 40 do not overcome the previously made rejections. The actual step of ablating is indeed independent of the approach angle. The approach

angle has everything to do with the type of target tissue site being ablated, the size and shape of the cavity into which the catheter elongated body member is inserted and how much the operator decide the steer/deflect the distal end portion of the catheter. The step of ablating has only to do with ablative device/tissue site proximity and ablative device energization (ablative energy activation).

Applicant points out on page 18, 2nd paragraph that the Lundquist et al. device is intended to penetrate the target tissue site. This is true and the examiner acknowledges this as fact. Applicant then goes onto detail how the amended claims over come Lundquist et al. by supplying the independence of the approach angle for ablation. However, for the reasons as described above, this amendment does distinguish over the prior art.

On page 19, paragraph 2, Applicant asserts that the Swanson et al. reference also lacks ablative ability independent of approach angle. As stated above, the examiner fully believes and has shown that the device disclosed by Swanson et al. can and does perform ablation independent of approach angle.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A.R. A.R.
January 5, 2004

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER